Lawrence D. Kelley, M.D. Susan Joth, D.O.

March 8, 1999

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U.S. Food & Drug Administration
Department of Health and Human Resources
Room 1061 HFA-305
5630 Fisher's Lane
Rockville, MD 20852

Re: Rezulin Advisory Committee Meeting

Gentlemen:

I am a general practitioner of medicine, practicing in Longwood, Florida and would like to go on record as supporting the use of Rezulin in the treatment of Type II diabetes. I was one of the first physicians to use this drug in patients and I have found it to be extremely efficacious. It has been remarkably safe. We have had only one lady whose liver function tests came into question in the past two years. This lady was on multiple medications. Since the institution of the new guidelines, we have monitored liver function tests on a monthly basis for at least eight months and have not found any other patients with elevated liver function tests.

It would, indeed, be a tragedy to have this drug withdrawn or for the usage to become so restrictive that doctors are afraid of it. To a certain extent, I feel that physicians are beginning to question this drug based on undue attention being focused on a small number of cases of liver failure and death. I would estimate that I have approximately 300-400 patients at present taking Rezulin. I would petition the committee to consider not only the bad, but also the good.

I would be glad to supply you further information as you might require.

Sincerely yours,

Lawrence D. Kelley, M.D.

LDK:paw

515 W. State Road 434, Ste. 308 98 P. 6622

Longwood, JL 32750

(407) 767-8500

LAWRENCE D. KELLEY, M.D. SUSAN TOTH, D.O.

FAMILY PRACTICE
DOCTORS MEDICAL BUILDING, SUITE 308
515 WEST STATE ROAD 434
LONGWOOD, FL. 32750



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